Managing Pharmaceutical Waste in California: Challenges and Opportunities

Management of Pharmaceutical Waste Workshop
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Agenda

- Proposed regulatory changes
- Quick review of pharmaceutical waste streams
- Implementing a pharmaceutical waste program at your facility
- THERE WILL BE A QUIZ!

Managing Pharmaceutical Waste: The Scope of the Problem

- ***Healthcare facilities***
  - ***Acute care hospitals***
  - Long term care facilities
  - Clinics/physicians' offices
  - Surgi-centers, etc.
- Retail pharmacies
  - Local and regional chains
  - National chains
  - Mail-order pharmacies
  - Long term care provider pharmacies
- Veterinary clinics
- ***Consumers***

Regulatory Bodies that Oversee Pharmaceutical Waste Management

- Environmental Protection Agency (EPA)
- State and County Environmental Protection and Health Agencies
- Department of Transportation (DOT)
- Drug Enforcement Administration (DEA)
- Occupational Safety and Health Administration (OSHA)
- Local Publicly Owned Treatment Works (POTW)

Immediate EPA Compliance Risk

- The U. S. EPA and state environmental protection agencies are increasing their enforcement of the Resource Conservation and Recovery Act (RCRA)
- Under RCRA, approximately 5% of pharmaceuticals become hazardous waste when the decision is made to discard them
- Compliant management requires a rigorous segregation, transport, treatment, and reporting system
- Corporate fines can be levied up to:
  - $37,500
  - Per violation, per day, per location
  - No statute of limitations
  - Civil and criminal liability

The Joint Commission Standards

- The Joint Commission has expanded their standards to include the management of hazardous medications
- Both the ***Environment of Care*** and ***Medication Management*** standards now require hospitals to appropriately manage the risks related to hazardous materials and waste
- Standard EC.02.02.01 The hospital manages risks related to hazardous materials and waste.
- Standard MM.01.01.03 The hospital safely manages high-alert and hazardous medications.

Proposed Regulatory Changes

- DEA: Amendment to Controlled Substances Act
- EPA: Office of Water BMPs
- EPA Office of Resource Conservation & Recovery: Universal Waste Rule

DEA: It Took an Act of Congress

Drug Enforcement Administration

- Regulates and enforces the provisions of the Controlled Substances Act
- Drugs of abuse are assigned to one of five "schedules"
- Schedule I: Illicit drugs such as heroin, methamphetamine
  - Medical marijuana - controversial
- Schedule II: Highly abused drugs such as OxyContin, Demerol, Vicodin
- Schedules III – V: Decreasing abuse potential; Valium, Robitussin with Codeine
- Disposal within a healthcare facility must be witnessed by two healthcare professionals and render the drug "non-recoverable"

2nd DEA National Drug Disposal Day: April 30, 2011

- Operated by regional Special Agent in Charge or other state DEA representative – disposal operations planned varied
- Law enforcement take-back programs only – compliant with existing CSA regulation – over 5300 sites registered
- State environmental regulations considered
- DEA covers cost of disposal, some free disposal
- ***NEW: DEA opens up April 2011 event to long term care facilities***
  - Somewhat controversial

Secure and Responsible Drug Disposal Act of 2010 (S.3397)

- Passed by Congress on September 28, 2010
- ***To amend the CSA to provide for the take-back disposal of controlled substances in certain instances***
- Findings:
  - Unintentional overdose deaths involving Rx opioids increased 114% from 2001 to 2005
  - Number of treatment admissions for Rx opioids increased 74% from 2002 to 2006
  - (related) Violent crime and property crime has increased in all regions of the US over the past 5 years
  - Teens abuse Rx drugs more than any illicit drug except marijuana
  - Drugs most often found in the home

Secure and Responsible Drug Disposal Act of 2010 (S.3397)

- Findings cont:
  - ***Long-term care facilities face a distinct set of obstacles to the safe disposal of controlled substances (not a DEA registrant, not able to use reverse distribution)***
  - Act gives the Attorney General authority to promulgate new regulations, within the framework of the Controlled Substances Act, ***that will allow patients to deliver unused pharmaceutical controlled substances to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion***
  - The goal of the Act: to encourage the Attorney General to set controlled substance diversion prevention parameters that will allow public and private entities to develop a variety of methods of collection and disposal of controlled substances…in a secure, convenient and responsible manner.

Secure and Responsible Drug Disposal Act of 2010 (S.3397)

- Section 302 of the CSA (21 U.S.C.822) is amended by adding at the end of the following:

"(g)(1) An ultimate user who has lawfully obtained a controlled substance in accordance with this title may, without being registered, deliver the controlled substance to another person for the purpose of disposal of the controlled substance if-

"(A) the person receiving the controlled substance is authorized under this title to engage in such activity; and

"(B) the disposal takes place in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances.

What Should DEA Regulations Encompass?
Or, The Devil's in the Details….

- DEA held hearings in Washington DC on Feb 19-20
- Consider new "registration" category for receipt, management and disposal of controlled substances: "Disposer" category
- Require an inventory and security procedures for containers of consolidated returns, but not at the capsule/tablet level of detail
- Form 41 modifications for witnessed incineration
- Enable current DEA registrants to add new registration with appropriate security concerns addressed
- Enable waste disposal companies to become registrants under "Disposer" category

Security of Transport for Collected Meds

- Kiosk collection:
  - Packaging from kiosk documented by two responsible parties
  - Package tracked and traced through receipt by final disposer
- Consumer mail-back:
  - Advance notification or call-tag type system
  - Package tracked and traced to final disposer
- Reverse distributor:
  - Advance notification or call-tag type system
  - Packages tracked and traced without opening through system and final witnessed burn (manage all as controlled substances)
- Community event:
  - Law enforcement continues to take controlled substances; other drugs shipped by waste vendor

16

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EPA Office of Water BMPs Draft Guidance

17

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EPA Published "Best Management Practices for Unused Pharmaceuticals at Health Care Facilities"

- EPA Office of Water requested public comments on a draft guidance document released in August, 2010
  - Sought input from over 700 stakeholders, reviewed disposal data from 20 hospitals and long term care facilities, visited 12 healthcare facilities, and reviewed literature data, reports, and state recommendations
- Targeted at hospitals, medical clinics, doctors' offices, long-term care facilities and veterinary facilities
- Goal: reduction in amount of pharmaceuticals that are discharged to water bodies
- Federal Register Notice published on Sept. 8th, 2010. Comments were due Nov. 8, 2010

18

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Primary Recommendations

- Identify and manage those drugs that become a hazardous waste in compliance with the EPA RCRA regulations
- ***Management of non-hazardous drug waste through incineration or landfilling – not down the drain***
- Manage controlled substances in a manner compliant with Drug Enforcement Administration regulations
  - Preference for reverse distribution when possible
  - Acknowledgement of potential necessity of drain disposal as last resort
- Manage radioactive drugs in compliance with Nuclear Regulatory Commission (NRC)

19

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Responses to EPA Draft Guidance

20

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Significant Concerns Expressed

- Many stakeholders responded via written and oral communications and meetings
- Primary concern was confusion due to lack of specific recommendations by type of facility e.g. hospital vs clinic vs long term care, etc.
- Some suggested practices not practical or necessary
- Some suggested practices already in place
  - Unit dose packaging at hospitals
  - Reverse distribution at facilities with pharmacies
- Due to large number of responses and requests for clarification by type of facility, ***final version most likely available end of summer, 2011***

21

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Summary on EPA BMPs

- Giant step in the right direction to reduce drain-disposal of drugs from healthcare facilities
- EPA will monitor industry response
- If industry responds, additional regulations unlikely
- If not….???
- California already ahead of this curve!

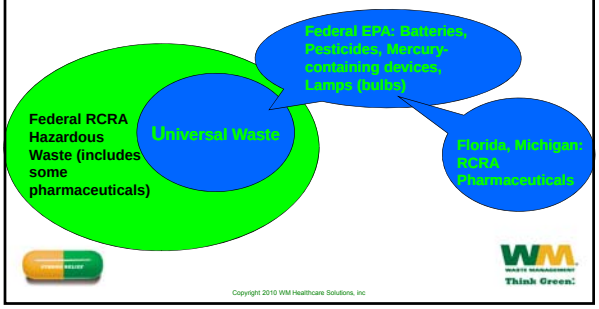
Whatever Happened to the Universal Waste Rule?

EPA Proposal to Add Pharmaceuticals to Universal Waste Rule

- Federal Register publication Dec 2, 2008 – Comments were due March 4, 2009
  - http://www.epa.gov/fedrgstr/EPA-WASTE/2008/December/Day-02/f28161.htm
  - Information: http://www.epa.gov/epawaste/hazard/wastetypes/universal/pharm.htm
- Proposed UWR only applies to drug waste that meets the definition of RCRA hazardous waste
- Only intended for healthcare-type generators, not manufacturers
- Intent to streamline pharmaceutical waste management and encourage consumer take-back programs
- WAS estimated end of 2011for federal enactment; states may or may not adopt

RCRA and Universal Waste

"Universal Waste" is a subset of RCRA hazardous waste.



Impact of Universal Waste Regulations

- Applies ONLY to 4% of drugs in the marketplace that are RCRA hazardous waste… does not address other 96% of drugs.
- Brings attention to the industry regarding the proper disposal of pharmaceutical waste.

Specific Benefits of Adding Pharmaceuticals to UWR

- **Hazardous pharmaceutical waste would no longer contribute to the generator size**
- Storage time limits would increase to one year total, allowing more time in storage accumulation area

Now Appears Unlikely that Hazardous Pharmaceutical Waste Will Be Added to UWR

EPA is currently reconsidering the proposed approach to improving management of pharmaceutical hazardous waste. Stakeholders commenting on the proposal expressed concerns over the ***lack of notification and tracking requirements for those facilities handling and transporting universal pharmaceutical wastes.*** In response to these concerns, the ***Agency has begun considering additional regulatory options to address the notification and tracking concerns as well as other issues that surround the proper management and disposal of hazardous pharmaceutical wastes.*** The Agency will have a better sense of a timeline as it further develops these other options.

Received from Lisa Lauer, USEPA, 3-21-2011

Some Potentially Good News…

- EPA is giving serious consideration to the impact of P-listed drug packaging such as warfarin wrappers and stock bottles and nicotine patch envelopes that significantly contribute to the generator status of a healthcare facility.

Review of Pharmaceutical Waste Streams, Containers, and Their Eventual Disposal

Which Discarded Drugs Become Hazardous Waste Under RCRA?

- P-listed chemicals (acutely hazardous)
  - Sole active ingredient; unused; empty containers
- U-listed chemicals (toxic)
  - Sole active ingredient; unused
- Chemicals with *characteristics* of hazardous waste
  - Ignitability
  - Toxicity
  - Corrosivity
  - Reactivity

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Examples of P-Listed Pharmaceutical Waste

Arsenic trioxide (chemo)	P012
Epinephrine base*	P042
Nicotine	P075
Nitroglycerin (weak)**	P081
Phentermine (CIV)	P046
Physostigmine	P204
Physostigmine Salicylate	P188
Warfarin >0.3%	P001

* Salts excluded federally as of Oct. 15th, 2007; California's Department of Toxic Substances Control (DTSC) has accepted this position

** Excluded from the P list federally and in California

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Examples of U-Listed Pharmaceutical Waste

Chloral Hydrate(CIV)	U034	*Melphalan*	U150
Chlorambucil	U035	*Mitomycin C*	U010
Cyclophosphamide	U058	*Streptozotocin*	U206
Daunomycin	U059	Selenium Sulfide	U205
Diethylstilbestrol	U089	*Uracil Mustard*	U237
Lindane	U129		

Drugs in red are chemotherapy agents

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Examples of U-Listed Pharmaceutical Waste


Which of the following statements about P-listed drugs is False?

A. Packaging is also disposed of as hazardous waste
B. They are acutely hazardous for humans
C. They have the characteristic of corrosivity
D. They are disposed of in black containers
E. They are regulated by the EPA

Answer: C

Characteristic of Ignitability

- Aqueous solution containing 24% alcohol or more by volume & flash point < 140° F
- Non-aqueous solutions with flash points < 140° F
- Oxidizers
- Flammable aerosols
- Hazardous waste code D001
- Examples:
  - Rubbing alcohol
  - Topical preparation: Clindamycin
  - Some injections: Paclitaxel

Characteristic of Corrosivity

- An aqueous solution having a pH ≤ 2 or ≥ 12.5
- Hazardous waste number: D002
- Examples: Primarily compounding chemicals
  - Glacial Acetic Acid
  - Sodium Hydroxide

Characteristic of Toxicity

- 40 chemicals which must be below specific leaching concentrations
- Fails the Toxicity Characteristic Leaching Procedure (TCLP)
- Must evaluate IVs, such as TPN
  - May come out of regulation due to dilution (chromium, selenium)
- Examples of potentially toxic pharmaceuticals:
  - Arsenic
  - Barium
  - Cadmium
  - Chromium
  - Lindane
  - M-Cresol
  - Mercury (thimerosal, phenylmercuric acetate)
  - Selenium
  - Silver

Additional Toxicity Evaluation

- Some pharmaceuticals that fail the TCLP when concentrated will pass when diluted
  - Selenium and Chromium when diluted in TPN
  - Insulin in an IV
- Mercury based preservatives always cause TCLP failure
  - Some manufacturers' processes also introduce thimerosal at levels that can cause failure
- Barium sulfate products may pass or fail, depending on the concentration
  - Only unused barium sulfate needs to be evaluated and managed

Examples of Pharmaceuticals Exhibiting the Characteristic of Toxicity

Preservatives: thimerosal & m-cresol

Heavy metals: selenium, chromium and silver

Characteristic of Reactivity

- Meet eight separate criteria identifying certain explosive and water reactive wastes
- The only potentially reactive pharmaceutical is nitroglycerin, but
  - Most weak nitroglycerin formulations may be considered excluded federally from the P081 listing as non-reactive as of August 14, 2001
  - Unless they exhibit another characteristics, such as ignitability
  - California also has an exclusion for weak nitroglycerin
- Hazardous waste number: D003

Chemotherapy Agents: Many Are Not Regulated by RCRA – Not Accounted for by MWMA

Nine (9) Chemotherapy agents are regulated by RCRA (1 P-listed; 8 U-Listed)

Examples:
Arsenic trioxide P012
Mitomycin C U010

Over 100 chemotherapy agents not regulated by EPA

Examples:
Alkylating agents: Cisplatin, Thiotepa
Antimetabolites: Fluorouracil, Methotrexate
Hormonal (antiandrogen): Lupron® (leuprolide)
Hormonal (antiestrogen): Tamoxifen
Mitotic Inhibitor: Taxol® (paclitaxol)

Three Types of Chemotherapy Waste

- Trace Chemotherapy Waste (yellow)
  - Medical waste hauler protocols for "Chemo Waste"
  - Empty vials, syringes, IV's, gowns, gloves, ziplock bags
  - Treated as infectious medical waste through regulated medical waste incineration
- "Bulk" Chemotherapy Waste (black)
  - If not empty, should be placed into RCRA Hazardous Waste container
- Spill Clean-up (black)
  - Manage as RCRA Hazardous Waste

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Definition of "Empty"

- "P" List

  Containers of "P" listed chemicals are considered hazardous waste, unless they have been rinsed three times and the rinsate discarded as hazardous waste.

- "U" List and D codes

  Containers of "U" listed chemicals or D codes are empty only when all contents removed that can be removed through normal means and no more than 3% by weight remains

  Example: "Empty" Cytoxan vial would be "trace" chemotherapy

- Residue of "P" or "U" listed drugs in a used syringe is exempted federally and by California and should be discarded as biohazardous waste or trace chemo, depending on the drug.

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What Is PharmE Hazardous® Waste?

- PharmEcology's best practice recommendations for identifying potentially hazardous pharmaceutical waste
- Drugs that are not legally RCRA hazardous but could be hazardous and should be managed as such
- Criteria
  - Chemotherapy drugs not currently listed in the regulations
  - EPA regulated pesticide
  - Iodine containing products
  - Pressurized aerosols
  - Poisons
- Recommend management as hazardous waste

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Satellite and Storage Accumulation Area

- RCRA hazardous waste container must be dated at the time waste is first placed into the container
- Total time in storage accumulation area is 90 days
- The total accumulation time available for the container in California is one year (combined satellite and storage areas)

Non-RCRA Hazardous Waste (The Waste Formerly Known as "California-Hazardous" Waste)

- Primary applicable criteria is an LD50 of 2500 mg/kg or less
- Acute aquatic 96-hour LC50 < 500mg/liter
- Carcinogenicity, acute toxicity, chronic toxicity, bioaccumulative, persistence in the environment
- No complete list
- Practical solution: manage all non-RCRA pharmaceuticals as Non-RCRA Hazardous

The Medical Waste Management Act and non-RCRA Hazardous Waste

- Causes pharmaceutical waste to be defined as "biohazardous" – out of sync with usual and customary definition as infectious waste
- Defines "empty" chemo container
- Defines pharmaceuticals as all drugs that are not RCRA and not radioactive
- Intent is to regulate non-RCRA haz waste; no way to discern exactly which non-RCRA drugs are hazardous in California, therefore manage all other drugs as non-RCRA Hazardous waste
- Requires incineration at a regulated medical waste facility or approved alternative

How Should Non-RCRA Hazardous Pharmaceutical Waste be Handled, Stored and Disposed?

- DPH prohibits sewering and landfilling of Non-RCRA Hazardous drugs
- Segregate into appropriate non-RCRA Pharmaceutical Waste container
- Label "Incinerate Only"
- Dispose at a regulated medical waste incinerator in accordance with the Medical Waste Management Act

Controlled Substances

- Controlled substances remain problematic in California.
- Normally sewered in other states
- Exceptions to sewering:
  - Used controlled substance patches such as fentanyl (they would clog pipes)
  - Waste controlled substances that are also federally hazardous waste such as chloral hydrate or phentermine, until permission is received from the local publicly owned treatment works (POTW).

Managing Controlled Substance Waste

- Conflicting messages from DPH, DEA
- Possible scenario:

  Small amounts of CS e.g. 2 ccs in a syringe: sewer with written permission from local POTW

  Larger amounts of CS e.g. 100 cc morphine drip: return to Pharmacy Dept. for reverse distribution
- Need consensus from both DPH and DEA

Implementation Guidelines From a Hospital's Perspective

52

Departments Involved in Managing Pharmaceutical Waste

- Pharmacy
- Nursing
- Environmental Services
- Safety
- Infection Control
- Facility Management
- Risk Management

- All with senior management support

53

Pharmaceutical Waste Management Program Components

- Establish pharmaceutical waste management program: Critical to have a designated champion, core team, project management, and launch packages
- Waste Categorization: Review of all drugs purchased by hospital, to identify those that become RCRA hazardous waste upon disposal
- Waste Collection and Segregation: Determine containers, satellite locations, labels, ADM messaging, storage accumulation set-up
- Waste transportation and disposal: Determine hauler and transport procedures
- Training: Conduct for management, nursing, pharmacy, and environmental services
- Pilot, launch, and sustain hospital-wide program.

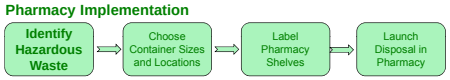
54

Key RCRA Implications for Hospital Staff

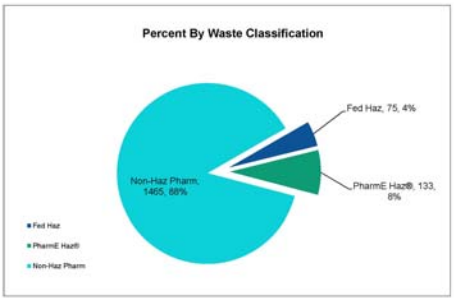
- Pharmacy will be responsible for providing an accurate inventory, for waste categorization, and for labeling of hospital pharmaceuticals.
- Nursing practices are most critical for the success of any program; all waste must be disposed of properly on the floors.
- Environmental Services will set up and maintain satellite accumulation areas and storage accumulation areas, and properly transport, store and ship the containers.

Pharmacy's First Task is to Identify Which Pharmaceuticals Becomes Hazardous Waste

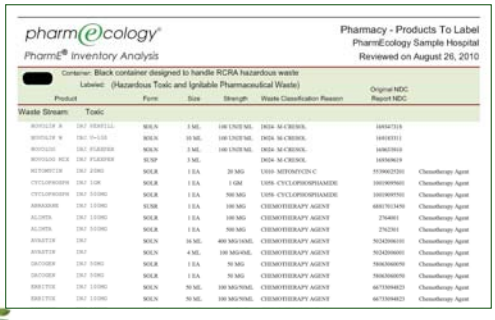
Pharmacy Implementation



The PharmE® Inventory Analysis: Summary By Waste Classification



Report: Products To Label


pharm@cology
Pharmacy - Products To Label
PharmEcology Sample Hospital
PharmE® Inventory Analysis
Reviewed on August 26, 2010
Container: Black container designed to handle RCRA hazardous waste
Labeled: (Hazardous Toxic and Ignitable Pharmaceutical Waste)
Product | Form | Size | Strength | Waste Classification Reason | Original NDC Report NDC
Waste Stream: Toxic

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Label the Shelves in Pharmacy


Pharmacy Implementation

Identify Hazardous Waste ⟹ Choose Container Sizes and Locations ⟹ **Label Pharmacy Shelves** ⟹ Launch Disposal in Pharmacy

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Maintain the system as new products are purchased

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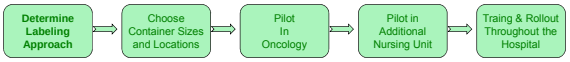
Implementation Guideline – From a Nursing Perspective

Nursing Implementation



61

Labeling Drugs Distributed to Nursing

- Pharmacy is also responsible for labeling the drugs distributed to Nursing. The key to success in any hospital hazardous waste management program is the degree to which Nursing participates, so proper labeling is very important
- There are policies and procedures for adding electronic messaging or cubie labels to
  - Automated dispensing machines (e.g. Pyxis, Accudose, Omnicell)
- There are policies and procedures for adding labels to
  - Shelves for pharmaceuticals in Nursing stations
  - Pharmaceuticals on delivery carts
  - Ointments and other multi-use medications
  - Prepared IVs

62

Role of Nursing in the Disposal of Pharmaceuticals

- Define prompts that will help nursing readily recognize hazardous pharmaceutical waste.
  - Messages on automated dispensing cabinets dispensing screens
  - Labeling bins / containers
  - Messages on the Bar Code Medication Administration (BCMA) dispensing screens
  - Messages on medication labels
- Select size, type, and location of containers that will be used to dispose of pharmaceutical waste

Where may the Containers be Located?

- Satellite Accumulation Area (point of generation)
  - Pharmacy
    - Sterile compounding area including chemo prep area
    - Throughout pharmacy as needed
  - Nursing units
    - Med room: Infection Control must be involved
    - Secured soiled utility room
    - Nurses station if under constant supervision
- Storage Accumulation Area (waiting for transport)
  - Managed by Environmental Services or Safety
  - Secured area removed from public access
  - Usually near loading dock

Why Segregate in the Pharmacy and Nursing Unit?

- Combined collection and segregation in the central storage area ***is not legal*** in California
- Non-RCRA Hazardous pharmaceutical waste is defined to be “biohazardous” in California
- Biohazardous waste cannot be segregated from other waste
- Therefore RCRA hazardous and Non-RCRA Hazardous waste must be segregated at the point of generation

Additional Consideration: Hazardous Waste is Compatible or Non-compatible

- Compatibles – Can be shipped together in same container without danger of reaction
- Non-compatibles - Cannot ship in same container because there is a potential for chemical reaction if co-mingled
  - Ignitable aerosols
  - Pressurized aerosols
  - Oxidizers
  - Reactives
  - Acids, Bases
- Non-compatibles are disposed of in a separate black container, or returned individually from nursing to pharmacy for processing.

Pharmaceutical Waste Containers:

- Federally hazardous waste
  - P-listed
  - U-listed
  - D codes - characteristic hazardous waste (Ignitability, Toxicity, Corrosivity, Reactivity)

- PharmE Hazardous® waste
- Non-compatible hazardous pharmaceutical waste
  - Aerosols,
  - Corrosive acids/bases
  - Oxidizers, reactives

Or

Return to Pharmacy

67

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Quick Check: Which of the following are considered non-compatibles and must be segregated separately from other hazardous waste? Select all that apply.

A. Aerosols
B. Acids
C. Bases
D. U-listed wastes
E. Oxidizers

Answer: A,B,C,E

68

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Dual Wastes

- "Dual Waste" refers to waste which is both federally hazardous under RCRA and biohazardous.
- Typically dual waste are RCRA wastes that remain in a full or partially used syringe with a needle.
- Example:
  - Physostigmine is drawn up in the OR prior to a surgical procedure and the drug is then not needed.
  - It inadvertently becomes a "dual waste."
- Dual wastes are disposed of in specialized black containers that can handle sharps.

69

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Satellite Accumulation

- Waste initially needs to be segregated, labeled and contained in areas where it is generated
- Make containers available in all units in which pharmaceutical waste is generated
- Label each black container as “Hazardous Waste” with the appropriate waste stream noted (toxic and ignitable, for example)
- There is a ONE YEAR time limit to fill the black container in California
- Must be moved to storage accumulation within three days when filled
- Ensure containers are kept securely closed unless adding or removing waste from the container

70

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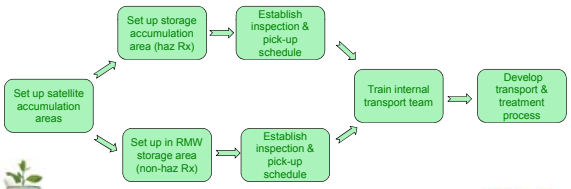
Implementation Guideline – From *Environmental Services’* Perspective

Follow-on Implementations in Environmental Services



71

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Creating a Hazardous Waste Profile

- Work with the hazardous vendor to create a certified hazardous waste profile of all toxic and ignitable drug waste
- Typical description for shipping commingled is:
  - UN3248, Waste Medicine, Liquid, Flammable, Toxic, n.o.s., 3 (6.1), PG II
- Ship any aerosols, corrosive acids, corrosive bases, or oxidizers separately
  - NOTE: The corrosive acids and bases referred to above are only for finished dosage forms that exhibit these characteristics, of which there are very few. ***If a bulk chemical is to be discarded, the hazardous waste vendor must evaluate each chemical and create a “lab pack.”*** These will NOT be placed into the black pharm waste containers but into a container provided by the vendor. The vendor will insure that incompatible chemicals are not packed in the same container

72

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DOT Hazardous Waste Label

- The initial Hazardous Waste label must be placed on the container BEFORE any waste is put into the container
- Upon reaching the storage accumulation area, write the storage accumulation date on the initial label
- At the time of shipping, the hazardous waste vendor will provide a completed DOT Hazardous Waste shipping label. Check to be certain all information is accurate and that all containers have this label affixed along with the hazard classes (for example, flammable and toxic) prior to leaving the facility

What is a Lab Pack?

- This term originated during the process of cleaning out old chemistry labs.
- It involves a trained chemist evaluating each chemical and determining if it can be packed safely with other chemicals for shipment
- All compatible chemicals (for example, all organic acids) are placed into one hazardous waste container with a compatible absorbent and labeled with the appropriate DOT shipping description and other appropriate labels.
- You will probably have lab packs from time to time as the pharmacy, laboratory, maintenance and other departments decide to discard chemicals no longer in use.

Hazardous Waste Generation Status

- **Large Quantity Generator** (LQG): generates more than 1000 kg/month of hazardous waste or >1 kg/month "P" listed waste or accumulates > 1 kg "P" listed waste
- **Small Quantity Generator** (SQG):Generates <1000 kg/month but >100 kg/month of hazardous waste & < or = 1 kg/month "P" listed waste.
- **Conditionally Exempt Small Quantity Generator** (CESQG) : Generates < or = 100 kg haz waste/month, < or = 1kg P listed waste/month
- **CESQG** NOT excluded from manifesting and reporting requirements in California

LQG Status Impacts Shipping

- If the monthly weight is at or greater than 1 kg (2.2 lbs) per month of P-listed waste, the organization is a **large quantity generator** (LQG) of hazardous waste.
- P-listed waste no longer must be segregated or monitored, but the organization must adhere to all requirements of a large quantity generator.
- While there is no need to record P waste separately, you must ship hazardous waste within 90 days of entering storage accumulation area

Spill Evaluation and Management

- Spill Evaluation
  - All employees that could be involved in drug spills must be trained on the steps to take to evaluate a spill, including who and when to call for assistance.
- Spill Management
  - The spill clean up materials from spills involving either RCRA hazardous waste or PharmE Hazardous© waste will be disposed in the hazardous waste container.
  - The spill clean up materials from spills involving non-hazardous pharmaceutical waste will be disposed either in the RCRA container or in the non-hazardous drug container designated for this purpose.

Documenting Generator Status

- Large quantity generator: no need to record P waste separately.
- Small or conditionally exempt small quantity generator: needs to segregate all P-listed including empty containers and document weights per calendar month
- Cannot exceed 1 kg or 2.2 lbs/month for any given month and cannot accumulates more than 1 kg P-listed waste

An Overview: Containers, Labeling, and Waste Streams

Four Common Color Coded Containers for Pharmaceutical Waste Collection

Hazardous Pharmaceutical Waste

Non-RCRA Hazardous Pharmaceutical Waste

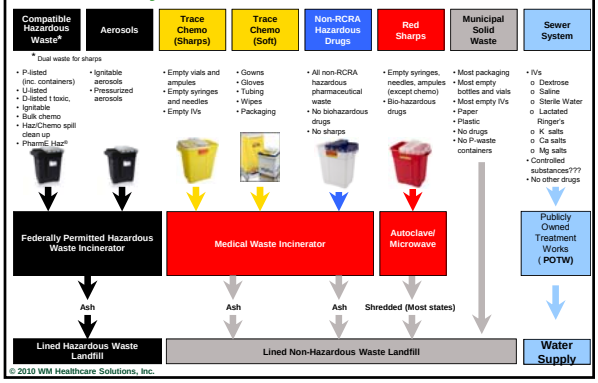
Trace Chemotherapy Waste

Regulated Medical Waste

Non-RCRA Hazardous Drugs Must Be Incinerated

- California Medical Waste Management Act prohibits drain disposal of “Non-RCRA Hazardous” drugs
- Most commonly sorted into a white container with blue top; Labeled “Incinerate Only”
- Segregate and incinerate at a regulated medical waste incinerator
- Controlled substances remain problematic

Summary of Pharmaceutical Waste Streams



Non-RCRA Hazardous pharmaceutical wastes should be disposed of in

A. Black containers
B. Blue and white containers
C. Sewers
D. Red containers
E. Solid Waste

Answer: B

Think Green!

Unresolved Issues Regarding Managing Pharmaceutical Waste in California

- Non-RCRA "bulk" chemotherapy waste (only trace chemotherapy waste is defined and regulated by the Medical Waste Management Act)
- Controlled substance disposal: healthcare facilities are caught between differing instructions from different agencies (and sometimes the same agency)
- Should truly "biohazardous" drugs be disposed in red or white containers? What about the empty containers?
- The definition of "pharmaceutical" in the MWMA includes all drugs not regulated elsewhere, whether or not they meet the criteria of Cal-Hazardous.

Think Green!

Quiz

Which of the following can be disposed of down the drain in California? Select all that apply.

A. Saline solutions
B. Unused prescription drugs
C. Chemotherapy drugs
D. P-listed drugs
E. U-listed drugs

- Answer: A

Which of the following can be disposed of with regular solid waste. Select all that apply.

A. Chemotherapy drugs
B. Unused prescription drugs
C. P-listed drugs
D. U-listed drugs
E. Most packaging, bottles, and cans if there is no recycling program in place

- Answer: E

Ignitability, Toxicity, Corrosivity, and Reactivity are characteristics of

A. P-listed pharmaceuticals
B. PharmE hazardous® pharmaceuticals
C. D coded pharmaceutical
D. Non-hazardous pharmaceuticals
E. U-listed pharmaceuticals

Answer: C

Black containers are used for

A. Hazardous drug waste regulated by RCRA and also PharmE Hazardous® waste
B. Sharps
C. Cal-Hazardous pharmaceutical wastes
D. Drugs regulated by DEA, the Drug Enforcement Administration

➢ Answer: A

Which of the following statements about U-listed drugs is False?

A. Packaging can be disposed of as solid waste
B. They are toxic for humans
C. They are usually disposed of in white and blue containers
D. Many are chemotherapy drugs
E. They are regulated by the EPA

➢ Answer: C

Summary

- Managing pharmaceutical waste in California in compliance with all applicable regulations is a complex management challenge.
- The regulatory community can provide assistance by meeting together to understand the challenges and by providing regulations and guidance that are internally consistent.

Questions?

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Resources

- NIOSH Hazardous Drug Alert
  - http://www.cdc.gov/niosh/docs/2004-165/#sum
- ASHP Guidance on Handling Hazardous Drugs
  - http://www.ashp.org/DocLibrary/BestPractices/PrepGdlHazDrugs.aspx
- OSHA Technical Manual
  - http://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html
- PGH Blueprint for Managing Pharm Waste in California
  - Blueprint on Pharmaceutical Waste Management (Revised) for California
  - http://www.bacwa.org/LinkClick.aspx?fileticket=dLjPqQLP5nI%3d&tabid=71&mid=415
- WMHS PharmEcology Services
  - www.pharmecology.com
  - FAQs, state and federal waste regulations, subscription search engine
  - PharmE® Waste Wizard identifies RCRA hazardous waste plus NIOSH hazardous drugs, among additional criteria

DEA Resources

- DEA Office of Diversion Control: http://www.deadiversion.usdoj.gov/
- Controlled Substance Schedules: http://www.deadiversion.usdoj.gov/schedules/index.html
- DEA Pharmacist's Manual: http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/index.html